

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Bengt-Ake Bengtsson	Title:	USE OF HUMAN GROWTH HORMONE IN MULTIPLE SYSTEM ATROPHY
App. No.:	10/595,076	Art Unit:	Not Yet Assigned
Conf. No.:	2186	Examiner:	Not Yet Assigned
Filing Date:	July 29, 2003		

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.97 and the continuing duty of disclosure under 37 C.F.R. § 1.56, Applicants call to the attention of the Examiner the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. It is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Forms PTO/SB/08A and PTO/SB/08B be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement is not to be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), this Information Disclosure Statement is not to be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement does not include copies of cited U.S. patents and U.S. patent publications pursuant to 37 C.F.R. 1.98(a)(2).

This Information Disclosure Statement is being filed prior to the receipt of a first Office Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b)(3).

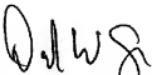
No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account 08-3038.

Respectfully submitted,

HOWREY LLP

Dated: November 7, 2006

By:



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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Complete If Known

Application Number	10/595,076
Filing Date	July 29, 2003
First Named Inventor	Bengt-Ake Bengtsson
Art Unit	1646
Examiner Name	Not yet assigned
Attorney Docket Number	05558.0036.PCUS00

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A1	Re 33,653		07/30/1991	Mark, et al.	
A2	4,588,585		05/13/1986	Mark, et al.	
A3	4,737,462		04/12/1988	Mark, et al.	
A4	4,904,584		02/27/1990	Shaw	
A5	4,959,314		09/25/1990	Mark, et al.	
A6	4,965,195		10/23/1990	Namen, et al.	
A7	5,017,691		05/21/1991	Lee, et al.	
A8	5,116,943		05/26/1992	Koths, et al.	
A9	5,137,872		08/11/1992	Seely, et al.	
A10	5,534,617		07/09/1996	Cunningham, et al.	
A11	5,597,709		01/28/1997	Rosen, et al.	
A12	5,612,470		03/18/1997	Thorner, et al.	
A13	5,633,352		05/27/1997	Dalboge, et al.	
A14	5,635,604		06/03/1997	Dalboge, et al.	
A15	5,654,010		08/05/1997	Johnson, et al.	
A16	5,688,666		11/18/1997	Bass, et al.	
A17	5,699,089		12/09/1997	Felix, et al.	
A18	5,721,250		02/24/1998	Morrillo, et al.	
A19	5,721,251		02/24/1998	Chen, et al.	
A20	5,723,616		03/03/1998	Houghton, et al.	
A21	5,726,307		03/10/1998	Schoen, et al.	
A22	5,726,319		03/10/1998	Lin, et al.	

Examiner Signature	/Christina Borgeest/ (04/03/2009)	Date Considered
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Sheet 2 of 3

Attorney Docket Number 05558.0036.PCUS00

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A23	5,731,317		03/24/1998	Lu, et al.	
A24	5,736,515		04/07/1998	Bengtsson, et al.	
A25	5,767,085		06/16/1998	Johansen, et al.	
A26	5,767,118		06/16/1998	Nargund, et al.	
A27	5,767,124		06/16/1998	Draper, et al.	
A28	5,773,441		06/30/1998	Hipskind, et al.	
A29	5,776,901		07/07/1998	Bowers, et al.	
A30	5,777,112		07/07/1998	Nargund, et al.	
A31	5,792,747		08/11/1998	Schally, et al.	
A32	5,795,957		08/18/1998	Deghenghi	
A33	5,798,337		08/25/1998	Somers, et al.	
A34	5,804,578		09/08/1998	Chakravarty, et al.	
A35	5,807,985		09/15/1998	Deghenghi	
A36	5,830,433		11/03/1998	Dean, et al.	
A37	5,834,598		11/10/1998	Lowman, et al.	
A38	5,843,453		12/01/1998	Holder, et al.	
A39	5,846,936		12/08/1998	Felix, et al.	
A40	5,847,066		12/08/1998	Coy, et al.	
A41	5,849,535		12/15/1998	Cunningham, et al.	
A42	5,849,700		12/15/1998	Sorensen, et al.	
A43	5,849,704		12/15/1998	Sorensen, et al.	
A44	5,851,992		12/22/1998	Sorensen	
A45	5,869,452		02/09/1999	Ng, et al.	
A46	6,143,523		11/07/2000	Cunningham, et al.	
A47	6,335,319		01/01/2002	Ng, et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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<i>Complete if Known</i>	
Application Number	10-595,076
Filing Date	July 29, 2003
First Named Inventor	Bengt-Ake Bengtsson
Art Unit	1646
Examiner Name	Not yet assigned
Attorney Docket Number	05558.0036.PCUS00

FOREIGN PATENT DOCUMENTS

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/595,076
				Filing Date	July 29, 2003
				First Named Inventor	Bengt-Ake Bengtsson
				Group Art Unit	1646
				Examiner Name	Not yet assigned
				Attorney Docket Number	05558.0036.PCUS00
Sheet	1	of	8		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	C1	Aberg, N. David, et al., "Growth Hormone Increases Connexin-43 Expression in the Cerebral Cortex and Hypothalamus*", Endocrinology, Vol. 141, No. 10, pp. 3879-3886 (2000)	
	C2	Adelman, J. P., et al., "In Vitro Deletional Mutagenesis for Bacterial Production of the 20,000-Dalton Form of Human Pituitary Growth Hormone," DNA (N.Y.), Vol. 2, No. 3, pp. 183-193 (1983)	
	C3	Alba-Roth, J., et al., "Arginine Stimulates Growth Hormone Secretion by Suppressing Endogenous Somatostatin Secretion," Journal of Clinical Endocrinology and Metabolism, Vol. 67, No. 6, pp. 1186-1189 (1988)	
	C4	Albertsson-Wikland, K., et al., "Daily Subcutaneous Administration of Human Growth Hormone in Growth Hormone Deficient Children," Acta Paediatr Scand, Vol. 75, pp.89-97 (1986)	
	C5	Altschul, S. F., et al., "Basic Local Alignment Search Tool," J. Mol. Biol., Vol. 215, pp. 403-410 (1990)	
	C6	Altschul, S. F., et al., "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search Programs," Nucleic Acids Research, Vol. 25, No. 17, pp. 3389-3402 (1997)	
	C7	Andersson, K., et al., "Rat Growth Hormone and Hypothalamic Catecholamine Nerve Terminal Systems, Evidence for Rapid and Discrete Reductions in Dopamine and Noradrenaline Levels and Turnover in the Median Eminence of the Hypophysectomized Male Rat," European Journal of Pharmacology, Vol. 95 pp. 271-275 (1983)	
	C8	Bandmann, O., et al., "Multiple-System Atrophy is Genetically Distinct from Identified Inherited Causes of Spinocerebellar Degeneration," Neurology, Vol. 49, pp. 1598-1604 (1997)	
	C9	Becker, G. W., et al., "Isolation and Characterization of a Sulfoxide and a Desamido Derivative of Biosynthetic Human Growth Hormone," Biotechnology and Applied Biochemistry, Vol. 10, pp. 326-337 (1988)	

Examiner Signature	/Christina Borgeest/ (04/03/2009)	Date Considered
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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	C10	Bewley, T. A., et al., "Sequence Comparison of Human Pituitary Growth Hormone, Human Chorionic Somatomammotropin, and Ovine Pituitary Growth and Lactogenic Hormones," Int. J. Peptide Protein Res., Vol. 4, pp. 281-287 (1972)	
	C11	Bowers, C. Y., et al., "On the Actions of the Growth Hormone-Releasing Hexapeptide, GHRP*," Endocrinology, Vol. 128, No. 4, pp. 2027-2035 (1991)	
	C12	Burman, P., et al., "Quality of Life in Adults with Growth Hormone (GH) Deficiency: Response to Treatment with Recombinant Human GH in a Placebo-Controlled 21-Month Trial," Journal of Clinical Endocrinology and Metabolism, Vol. 80, No. 12, pp. 3585-3590 (1995)	
	C13	Camanni, F., et al., "Growth Hormone-Releasing Peptides and Their Analogs," Frontiers in Neuroendocrinology, Vol. 19, pp. 47-72 (1998)	
	C14	Chen, E. Y., et al., "The Human Growth Hormone Locus: Nucleotide Sequence, Biology, and Evolution," Genomics, Vol. 4, pp. 479-497 (1989)	
	C15	Daniel, S. E., "The Neuropathology and Neurochemistry of Multiple System Atrophy," Mathias CJ, Bannister R eds. Autonomic Failure: A Textbook of The Autonomic Nervous System, 4 th ed., Oxford University Press, pp. 321-328 (1999)	
	C16	DeNoto, F., et al., "Human Growth Hormone DNA Sequence and mRNA Structure: Possible Alternative Splicing," Nucleic Acids Research, Vol. 9, No. 15, pp. 3719-3730 (1981)	
	C17	Devereux, J., et al., "A Comprehensive Set of Sequence Analysis Programs for the VAX," Nucleic Acids Research, Vol. 12, No. 1, pp. 387-395 (1984)	
	C18	Eccken, H. V., et al., "Striopallidal-Nigral Degeneration, An Hitherto Undescribed Lesion in Paralysis Agitans," American Association of Neuropathologists, Vol. 19, pp. 159-161 (1960)	

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	C19	Felix, A. M., et al., "Pegylated Peptides IV Enhanced Biological Activity of Site-Directed Pegylated GRF Analogs," Int. J. Peptide Protein Res., Vol. 46, pp. 253-264 (1995)	
	C20	Friend, K., et al., "Pyridostigmine Treatment Selectively Amplifies the Mass of GH Secreted per Burst Without Altering GH Burst Frequency, Half-Life, Basal GH Secretion or the Orderliness of GH Release," European Journal of Endocrinology, Vol. 137, pp. 377-386 (1997)	
	C21	Gertler, A., et al., "Inhibition of Lactogenic Activities of Ovine Prolactin and Human Growth Hormone (hGH) by a Novel Form of a Modified Recombinant hGH*", Endocrinology, Vol. 118, No. 2, pp. 720-726 (1985)	
	C22	Ghigo, E., et al., "Orally Active Growth Hormone Secretagogues: State of the Art and Clinical Perspectives," Annals of Medicine Vol. 30, pp. 159-168 (1998)	
	C23	Gilman, S., et al., "Consensus Statement on the Diagnosis of Multiple System Atrophy," Journal of the Autonomic Nervous System, Vol. 74, pp. 189-192 (1998)	
	C24	Goeddel, D. V., et al., "Direct Expression in <i>Escherichia coli</i> of a DNA Sequence Coding for Human Growth Hormone," Nature, Vol. 281, pp. 544-548 (1979)	
	C25	Graft, L., et al., "Human Somatotropin," The Journal of Biological Chemistry, Vol. 257, No. 5, pp. 2365-2369 (1982)	
	C26	Grantham, R., "Amino Acid Difference Formula to Help Explain Protein Evolution," Science, Vol. 185, pp. 862-864 (1974)	
	C27	Harvey, S., et al., "Growth Hormone: Neurocrine and Neuroendocrine Perspectives," Growth Regulation, Vol. 3, pp. 161-171 (1993)	

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	C28	Holmberg, B., et al., "Increased Cerebrospinal Fluid Levels of Neurofilament Protein in Progressive Supranuclear Palsy and Multiple-System Atrophy Compared with Parkinson's Disease," <i>Movement Disorders</i> , Vol. 13, No. 1, pp. 70-77 (1998)	
	C29	Hsiung, H. M., et al., "Use of Bacteriocin Release Protein in <i>E. Coli</i> For Excretion of Human Growth Hormone into the Culture Medium," <i>Biotechnology</i> , Vol. 7, pp. 267-271 (1989)	
	C30	Hughes, A. J., et al., "Apomorphine Test to Predict Dopaminergic Responsiveness in Parkinsonian Syndromes," <i>The Lancet</i> , Vol. 336, pp. 32-34 (1990)	
	C31	Hughes, A. J., et al., "Challenge Tests to Predict the Dopaminergic Response in Untreated Parkinson's Disease," <i>Neurology</i> , Vol. 41, pp. 1723-1725 (1991)	
	C32	Hughes, A. J., et al., "The Dopaminergic Response in Multiple System Atrophy," <i>Journal Of Neurology, Neurosurgery, and Psychiatry</i> , Vol. 55, pp. 1009-1013 (1992)	
	C33	Johansson, J-O., et al., "Growth Hormone and Psychosocial and Central Nervous Effects," <i>Growth Hormone in Adults-Physiological and Clinical Aspects</i> , 2 nd edition, Cambridge University Press, pp. 349-372 (2000)	
	C34	Jorgensen, K. D., et al., "Pharmacokinetics of Biosynthetic and Pituitary Human Growth Hormones in Rats," <i>Pharmacology & Toxicology</i> , Vol. 63, pp. 129-134 (1988)	
	C35	Kimber, J. R., et al., "Distinction of Idiopathic Parkinson's Disease from Multiple-System Atrophy by Stimulation of Growth-Hormone Release with Clonidine," <i>The Lancet</i> , Vol. 349, pp. 1877-1881 (1997)	
	C36	Kimber, J., et al., "Physiological, Pharmacological and Neurohormonal Assessment of Autonomic Function in Progressive Supranuclear Palsy," <i>Brain</i> , Vol. 123, pp. 1422-1430 (2000)	

Examiner Signature	/Christina Borgeest/ (04/03/2009)	Date Considered
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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/595,076
				Filing Date	July 29, 2003
				First Named Inventor	Bengt-Ake Bengtsson
				Group Art Unit	1646
				Examiner Name	Not yet assigned
				Attorney Docket Number	05558.0036.PCUS00
Sheet	5	of	8		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	C37	Klein, C., et al., "The 'Cold Hands Sign' in Multiple System Atrophy," Movement Disorders, Vol. 12, No. 4, pp. 514-518 (1997)	
	C38	Kraft, E., et al., "The Combination of Hypointense and Hyperintense Signal Changes on T ₂ -Weighted Magnetic Resonance Imaging Sequences," Archives of Neurology, Vol. 56, pp. 225-228 (1999)	
	C39	Lewis, et al., "Hyperglycemic Activity of Growth Hormone," Endocrinology, Vol. 101, No. 5, pp. 1588-1603 (1977)	
	C40	Lewis, U. J., et al., "A Naturally Occurring Structural Variant of Human Growth Hormone*," The Journal of Biological Chemistry, Vol. 253, No. 8, pp. 2679-2687 (1978)	
	C41	Lewis, U. J., et al., "Altered Proteolytic Cleavage of Human Growth Hormone as a Result of Deamidation*," The Journal of Biological Chemistry, Vol. 256, No. 22 pp. 11645-11650 (1981)	
	C42	Lewis, U. J., et al., "Human Growth Hormone: Additional Members of the Complex," Endocrinology, Vol. 104, No. 5, pp. 1256-1265 (1979)	
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	C44	Litvan, I., et al., "Clinical Research Criteria for the Diagnosis of Progressive Supranuclear Palsy (Stein-Richardson-Olszewski Syndrome): Report of the NINDS-SPSP International Workshop," Neurology, Vol. 47, pp. 1-9 (1996)	
	C45	Litvan, I., et al., "What Is the Accuracy of the Clinical Diagnosis of Multiple System Atrophy?" Archives of Neurology, Vol. 54, pp. 937-944 (1997)	
	C46	Martial, J. A., et al., "Human Growth Hormone: Complementary DNA Cloning and Expression in Bacteria," Science, Vol. 205, pp. 602-607 (1979)	
	C47	Meinkoth, J., et al., "Hybridization of Nucleic Acids Immobilized on Solid Supports," Analytical Biochemistry, Vol. 138, pp. 267-284 (1984)	

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			Filing Date	July 29, 2003	
			First Named Inventor	Bengt-Ake Bengtsson	
			Group Art Unit	1646	
			Examiner Name	Not yet assigned	
Sheet	6	of	8	Attorney Docket Number 05558.0036.PCUS00	

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published			T ²
	C48	Moore, J. A., et al., "Equivalent Potency and Pharmacokinetics of Recombinant Human Growth Hormones With or Without an N-Terminal Methionine," <i>Endocrinology</i> , Vol. 122, No. 6, pp. 2920-2926 (1988)			
	C49	Pearson, W. R., "Rapid and Sensitive Sequence Comparison with FASTP and FASTA," <i>Methods in Enzymology</i> , Vol. 183, pp. 63-99 (1990)			
	C50	Pearson, W. R., et al., "Improved Tools for Biological Sequence Comparison," <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 85, pp. 2444-2448 (1988)			
	C51	Polo, K. B., et al., "Botulinum Toxin-A Improves the Rigidity of Progressive Supranuclear Palsy," <i>Annals of Neurology</i> , Vol. 35, pp. 237-239 (1994)			
	C52	Quinn, N, "Multiple System Atrophy—The Nature of The Beast," <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> . Special Supplement, pp.78-89 (1989)			
	C53	Raizada, M. K., et al., "The Role of Insulin-Like Growth Factors in the Nervous System," <i>Annals of the New York Academy of Sciences</i> , Vol. 692, pp. 10-21 (1993)			
	C54	Rosengren, L. E., et al., "A Sensitive ELISA for Glial Fibrillary Acidic Protein: Application in CSF of Adults," <i>Journal of Neuroscience Methods</i> , Vol. 51, pp. 197-204 (1994)			
	C55	Rosengren, L. E., et al., "Glial Fibrillary Acidic Protein in CSF of Multiple Sclerosis Patients: Relation to Neurological Deficit," <i>Journal of the Neurological Sciences</i> , Vol. 133, pp. 61-65 (1995)			**
	C56	Rosengren, L. E., et al., "Neurofilament Protein Levels in CSF are Increased in Dementia," <i>Neurology</i> , Vol. 52, pp. 1090-1093 (1999)			
	C57	Rosengren, L. E., et al., "Patients with Amyotrophic Lateral Sclerosis and Other Neurodegenerative Diseases Have Increased Levels of Neurofilament Protein in CSF," <i>Journal of Neurochemistry</i> , Vol. 67, pp. 2013-2018 (1996)			

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

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Complete if Known

Application Number	10/595,076
Filing Date	July 29, 2003
First Named Inventor	Bengt-Ake Bengtsson
Group Art Unit	1646
Examiner Name	Not yet assigned
Attorney Docket Number	05558.0036.PCUS00

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	J ²
	C58	Rossi, P., et al., "Acute Challenge with Apomorphine and Levodopa in Parkinsonism," European Neurology, Vol. 43, pp. 95-101 (2000)	
	C59	Schrag, A., et al., "Clinical Usefulness of Magnetic Resonance Imaging in Multiple System Atrophy," Journal Of Neurology Neurosurg. Psychiatry, Vol. 65, pp. 65-71 (1998)	
	C60	Singh, R. N. P., et al., "Modified Forms of Human Growth Hormone with Increased Biological Activities," Endocrinology, Vol. 94, No. 3, pp. 883-891 (1974)	
	C61	Smith, R. G., et al., "A Nonpeptidyl Growth Hormone Secretagogue," Science, Vol. 260, pp. 1640-1643 (1993)	
	C62	Smith, T. F., et al., "Comparison of Biosequences," Advances in Applied Mathematics, Vol. 2, pp. 482-489 (1981)	
	C63	Tannenbaum, G., "Evidence for Autoregulation of Growth Hormone Secretion Via The Central Nervous System," Endocrinology, Vol. 107, No. 6, pp. 2117-2120 (1980)	
	C64	Thorlacius-Ussing, O., "Zinc in the Anterior Pituitary of Rat: A Histochemical and Analytical Work," Neuroendocrinology, Vol. 45, pp. 233-242 (1987)	
	C65	Thorner, M. O., et al., "Growth Hormone-Releasing Hormone and Growth Hormone-Releasing Peptide as Therapeutic Agents to Enhance Growth Hormone Secretion in Disease and Aging," Recent Progress in Hormone Research, Vol. 52, pp. 215-246 (1987)	
	C66	Wenning, G. K., et al., "Minimal Change Multiple System Atrophy," Movement Disorders, Vol. 9, No. 2, pp. 161-166 (1994)	
	C67	Wenning, G. K., et al., "Multiple System Atrophy: A Review of 203 Pathologically Proven Cases," Movement Disorders, Vol. 12, No. 2, pp. 133-147 (1997)	

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			Filing Date	July 29, 2003
			First Named Inventor	Bengt-Ake Bengtsson
			Group Art Unit	1646
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			Attorney Docket Number	05558.0036.PCUS00

Sheet 8 of 8

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	C68	Wenning, G. K., et al., "Olivopontocerebellar Pathology in Multiple System Atrophy," Movement Disorders, Vol. 11, No. 2, pp. 157-162 (1996)	

Examiner Signature	/Christina Borgeest/ (04/03/2009)	Date Considered	
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